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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/991,809

11/23/2001

George Jackowski

2132.111

5604

21917 7590 01/30/2007  
MCHALE & SLAVIN, P.A.  
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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/991,809

Applicant(s)

JACKOWSKI ET AL.

Examiner

Deborah A. Davis

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1655

### **DETAILED ACTION**

Applicants' response to the Office Action mailed on October 20, 2006 has been acknowledged. Currently, claim 1 is pending and under consideration.

The text of those sections of Title 35, US Code not included in this action can be found in a prior Office Action.

**The following rejections are being maintained:**

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, credible or a well established utility.

Applicant has identified band 6 of SEQ ID NO: 1 in Figure I of the drawings. Applicant's have disclosed in the remarks/arguments (page 26, paragraphs 1-2) that the biopolymer marker is present in only the diabetes II patients and not in the normal patients. However, in Figure I of the drawings, the biopolymer marker appears to be expressed in both normal and diabetes II patients. Therefore the differential expression of SEQ ID NO: 1 is not evident and the data results are ambiguous. The examiner maintains that the correlation with respect to diabetes II is not exemplified or disclosed in the specification in a way that one of ordinary skill in the art could distinguish the

Art Unit: 1655

differential expression in a diabetes II patient versus a normal patient. Therefore, one of ordinary skill in the art would not be able to distinguish a credible and specific or well established utility that SEQ I.D. No. 1 is linked to diabetes II. Although the MPEP does not require examples, however, the teaching provided must be substantial enough to enable one of ordinary skill in the art to ascertain the credibility of the evidence presented. Accordingly, the specification does not identify a substantial, credible or well-established utility for sequence consisting of SEQ ID NO: 1.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Response to Arguments***

Applicant's arguments filed October 20, 2006 have been fully considered but they are not persuasive:

Applicant argues that the courts rarely sustain a 101 rejection because an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement and should presume that a statement of utility made by an applicant is true. Applicant present supporting articles to further support the position taken. Applicant's argument is noted but not found to be persuasive.

In response, in the context of determining whether sufficient utility has been  
alleged it is proper for the examiner to ask for substantiating evidence unless one with

Art Unit: 1655

ordinary skill in the art would accept the allegations as obviously correct.” *In re Jolles*, 628 F.2d 1322, 1332 [206 USPQ 885] (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 [134 USPQ 335] (CCPA 1962); see *Application of Irons*, 340 F.2d 974, 977-78 [144 USPQ 351] (CCPA 1965). Indeed, in *In re Brana*, 51 F.3d 1560 [34 USPQ2d 1436] (Fed. Cir. 1995), we stated that “a specification disclosure which contains a teaching of the manner and process of making and using the invention ... must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” *Id.* at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 [169 USPQ 367] (CCPA 1971); *Fiers v. Revel*, 984 F.2d 1164, 1171-72 [25 USPQ2d 1601] (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Application of Armbruster*, 512 F.2d 676, 677 [185 USPQ 152] (CCPA 1975); *Application of Knowlton*, 500 F.2d 566, 571 [183 USPQ 33] (CCPA 1974); *Application of Bowen*, 492 F.2d 859 [181 USPQ 48] (CCPA 1974); *Application of Hawkins*, 486 F.2d 569, 576 [179 USPQ 157] (CCPA 1973). However, where there is “no indication that one skilled in [the] art would accept without question, statements of the utility of the biopolymer marker since conflicting evidence has been presented to demonstrate that the claimed marker do have those effects,” (i.e. is present in the diabetes sample and not in the normal) an applicant has failed to demonstrate credible utility and therefore cannot establish enablement. *Novak*, 306 F.2d at 928.

Applicant’s specification of utility is conflicting with the information provided by the drawing. As stated in the previous rejection, the biopolymer marker is present in

Art Unit: 1655

normal as well as diabetes II samples. Such conflicting information does not provide a substantial or credible utility.

Applicant argues that the examiner must show that the asserted utility is wholly inconsistent with contemporary knowledge in the art. This argument is noted but not found to be persuasive.

In response, the examiner does not doubt what is well known in the art that specific biomarker proteins found to be differentially expressed between disease and normal are frequently identified as targets for diagnostics. What the examiner sees as conflicting is the credibility of the marker that is present in normal and disease samples. Since applicant's sequence is free of the prior art, the examiner rely on information in the specification and other data (i.e. drawings if provided) to provide sufficient teaching of substantial and credible utility. As provided by the arguments above, applicant's specification and drawing provide conflicting information. Because applicant has not provided a substantial and credible utility, one of ordinary skill in the art would not know how to use the claimed marker. Therefore, the rejection is hereby maintained and made final.

### ***Conclusion***

No claims are allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1655

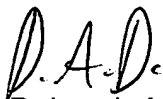
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

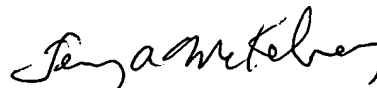
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McKelvey Terry can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah A. Davis  
Patent Examiner  
Art Unit 1655  
January 2007



TERRY MCKELVEY, PH.D.  
SUPERVISORY PATENT EXAMINER